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10/551,293

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Debbie Stevens-Wright

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EXAMINER

LEE, BENJAMIN HYOUNGSOL

ART UNIT

PAPER NUMBER

3739

MAIL DATE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/551,293	Applicant(s) STEVENS-WRIGHT ET AL.	
	Examiner BENJAMIN LEE	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 October 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-7,11-13,16-19 and 32-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-7,11-13,16-19 and 32-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. In response to the amendment filed on 10/8/2009, claims 1, 3-7, 11-13, 16-19 and 32-34 are pending, and claims 2, 8-10, 14-15, 20-31 are canceled.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. **Claim 18** is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 18 recites the limitation "the first ablation electrode and the second ablation electrode". There is insufficient antecedent basis for this limitation in the claim. The claim should be amended to --the first ablation electrode portion and the second ablation electrode portion--.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

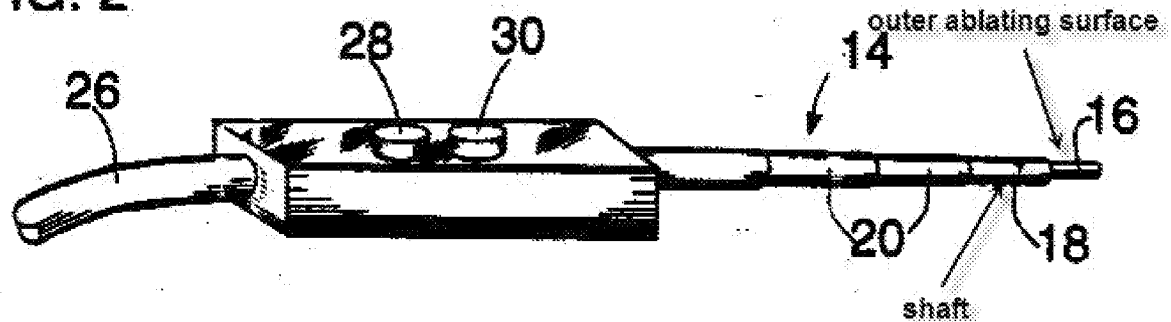
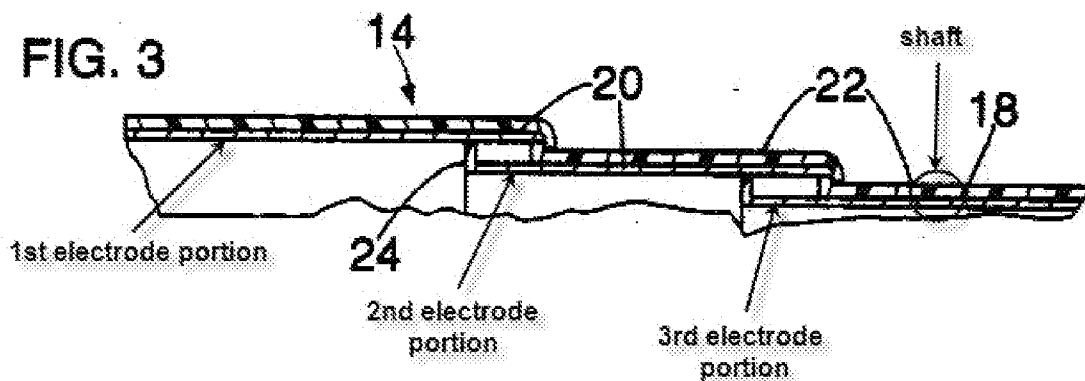
4. **Claims 1, 4, 6-7 and 33** are rejected under 35 U.S.C. 102(b) as being anticipated by Goldhaber (U.S. Patent No. 5,234,429).

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As to claim 1, Goldhaber discloses a catheter comprising a longitudinal catheter shaft (as labeled in Figs 2 & 3 below) for positioning an ablation electrode 14 within a patient's body (col. 1, lines 14-19). The ablation electrode is disposed on the shaft and has an outer ablating surface 16 (see Fig. 2 below). The electrode is convertible from a first configuration in which the electrode outer ablating surface 16 has a first axial size and a first radial size to a second configuration in which the electrode outer ablating surface 16 has a second axial size and maintains the first radial size (compare Figs. 1 & 2, col. 2, lines 46-53). The ablation electrode comprises a first electrode portion and a second electrode portion (as labeled below), the second portion having a length and being moveable in the axial direction of the catheter (Figs. 1 & 2, col. 3, lines 32-37), wherein in the first configuration more of the second electrode portion length is contained within the first electrode portion than in the second configuration as inferred from Figs 1 & 2.

Note that the limitations of claim 1 do not preclude the possibility of an insulation layer over the electrode as seen in Fig. 3. The claim does not specify that the **entire** ablation electrode has an ablating surface. The claim is interpreted broadly such that the ablation electrode may have a portion that has an ablating surface.

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FIG. 2**FIG. 3**

As to claim 4, Goldhaber teaches the ablation electrode comprises a third electrode portion that is at least partially contained within the second electrode portion in the first configuration (see Fig. 3 above).

As to claim 6, Goldhaber teaches that the ablation electrode is a ring electrode since the electrode has a ring shape as shown in Figs. 1 & 2.

As to claim 7, Goldhaber teaches that the first electrode portion and the second electrode portion are cylindrical since they are tubular (Figs. 2 & 3, col. 3, lines 9-12).

As to claim 33, Goldhaber teaches the first electrode portion is in electrical contact with an electrical lead 24, and the second electrode portion is in electrical contact with the same electrical lead (Fig. 3, col. 3, lines 15-18).

5. **Claims 11 and 34** are rejected under 35 U.S.C. 102(b) as being anticipated by Silvestrini (WO 95/20360).

As to claim 11, Silvestrini teaches a catheter with a longitudinal catheter shaft 5 (Fig. 3) for positioning an ablation electrode within a patient's body (pg. 1, ¶ 1). Silvestrini teaches an ablation electrode 2 (that inherently has a length) is disposed on the shaft 5, and the electrode 2 has a continuous outer ablating surface area with an outer ablating surface area length since the electrode's surface area is connected to an RF generator (see Fig. 3, pg. 8, ¶ 2). The outer ablating surface area length and ablation electrode length (which are identical) are adjustable since in one embodiment an insulating sheath slides relative to the electrode and adjustably exposes a portion of the electrode (page 3, line 33 – page 4 line 2) and in another embodiment the electrode portions are telescopically slidable relative to one another (pg. 8, ¶ 3), thus exposing or hiding surface area of the ablation electrode. Silvestrini teaches the electrode is substantially comprised of metal since it is fabricated from conventional metallic electrode material (pg. 3, ¶ 3).

As to claim 34, Silvestrini teaches in Fig. 3 a catheter comprising: a longitudinal catheter shaft 5 for positioning an ablation electrode within a patient's body; and an electrically conductive element 2 disposed on the shaft and connectable to an energy

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supply, an exposed portion of the electrically conductive element being usable as an ablation electrode, wherein the exposed portion of the electrically conductive element is convertible from a first configuration, in which the electrically conductive element has a first axial length and a first radial size along a first axial section of the shaft, to a second configuration in which the exposed portion of the electrically conductive element has a second, longer axial length and maintains the first radial size along the first axial section of the shaft since in one embodiment an insulating sheath slides relative to the electrode and adjustably exposes a portion of the electrode (page 3, line 33 – page 4 line 2). In another embodiment, the electrode slides relative to another electrode (pg. 8, ¶ 3).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. **Claim 3** is rejected under 35 U.S.C. 103(a) as being unpatentable over Goldhaber (USPN 5,234,429), as applied to claim 1 above, in view of Silvestrini (WO 95/20360).

As to claim 3, it is possible that the device of Goldhaber is capable of having the first configuration wherein the second electrode portion length is fully contained within the second electrode portion in the first configuration since the electrode portions are

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retractable (Figs. 1 & 2, col. 3, lines 32-37). Furthermore, one of ordinary skill in the art would appreciate such a feature as demonstrated by Silvestrini who teaches a similar device by comparing Figs. 1 and 2. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to implement the device of Goldhaber such that in the first configuration, the second electrode portion length is fully contained within the second electrode portion in the first configuration, since Silvestrini teaches this feature (Figs. 1 & 2) and in order to minimize the total length of the device for certain procedures.

As to claim 5, Goldhaber does not expressly teach a pull wire is connected to the second electrode portion. However, one of ordinary skill in the art would appreciate the alternative method of retracting such devices by implementing a pull wire to control the device, as demonstrated by Silvestrini. Silvestrini teaches a wire that is connected to a second electrode portion (pg. 7, ¶ 2) and is capable of being pulled or pulling the second electrode portion since it steers the second electrode portion. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to implement a pull wire connected to the second electrode portion of Goldhaber since one of ordinary skill in the art would appreciate the alternative method of controlling the device, as demonstrated by Silvestrini (pg. 7, ¶ 2), and in order to control retraction of the device of Goldhaber.

8. **Claims 12-13** are rejected under 35 U.S.C. 103(a) as being unpatentable over Silvestrini (WO 95/20360), as applied to claim 11 above, in view of Eggers (U.S. Patent 5,810,764).

As to claim 12, Silvestrini does not expressly teach that the electrode is substantially comprised of at least one of platinum, silver, gold, chromium, aluminum and tungsten. However, Eggers teaches that electrodes for ablation comprise electrically conducting materials such as alloys containing one or more of platinum, chromium, aluminum or tungsten (col. 22, lines 49-53). It would have been obvious to one of ordinary skill in the art at the time of the invention to implement the electrode of Silvestrini such that it substantially comprised of at least one of platinum, silver, gold, chromium, aluminum or tungsten since suitable metallic materials for an ablation electrode is recognized in the art, as exemplified by the teachings of Eggers (col. 22, lines 49-53).

As to claim 13, Silvestrini does not expressly teach that the electrode is substantially comprised of a combination of at least two of: platinum; silver; gold; chromium; aluminum and tungsten. However, Eggers teaches that electrodes for ablation comprise electrically conducting materials such as alloys containing one or more of platinum, chromium, aluminum or tungsten (col. 22, lines 49-53). It would have been obvious to one of ordinary skill in the art at the time of the invention to implement the electrode of Silvestrini such that it substantially comprised of a combination of at least two of platinum, silver, gold, chromium, aluminum or tungsten since suitable

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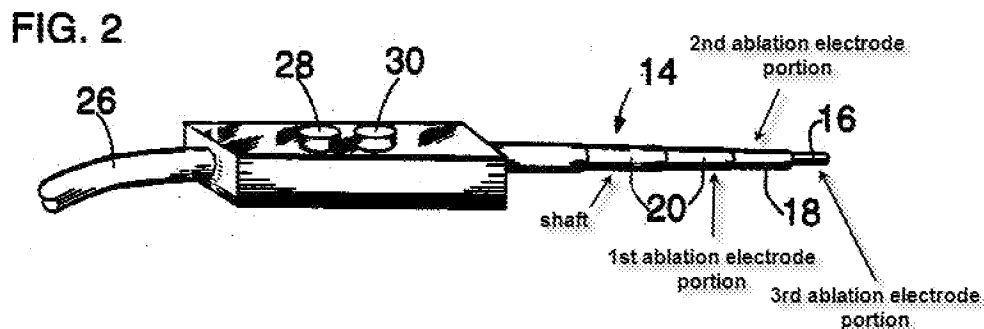
metallic combinations for an ablation electrode is recognized in the art, as exemplified by the teachings of Eggers (col. 22, lines 49-53).

9. **Claims 16-18 and 32** are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldhaber (USPN 5,234,429), in view of Turkel (USPN 5,354,296).

As to claim 16, Goldhaber teaches an ablation electrode 14 for ablating tissue (col. 1, lines 14-19) comprising a first ablation electrode portion configured for mounting on a catheter shaft (see Fig. 2 below). The first electrode portion is called a first ablation electrode portion since it is electrically connected to the ablating operative tip 16. The first ablation electrode portion has an outer surface configured to emit electrical energy since it is electrically connected to the supply line carrying the appropriate waveform (col. 3, lines 19-23). A second ablation electrode portion is configured for mounting on the inner surface of the catheter shaft in an indirect manner as seen in Fig. 1 and has a surface configured to emit electrical energy since it is electrically connected to the supply line carrying the appropriate waveform (col. 3, lines 19-23). The second ablation electrode portion is moveable from a first position substantially inside the first ablation electrode portion to a second position substantially outside the first ablation electrode portion as shown in Figs 1 & 2 (col. 3, lines 32-37). Goldhaber discloses the first and second ablation electrode portions do not have outer ablating surfaces since they are covered with insulation (see Fig. 3). However, one of ordinary skill in the art would appreciate modifying the device of Goldhaber such that the insulation is removed to expose the ablating surfaces of the electrode portions. Such a configuration is seen in

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the telescoping ablation device of Turkel in Figs. 3a-b. The electrode 304 of Turkel comprises multiple electrode portions with outer ablating surfaces in a telescoping manner. Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to implement the first and second ablation electrode portions of Goldhaber with outer ablating surfaces since Turkel teaches a similar configuration of electrodes (Figs 3a-b, col. 4, lines 15-24) and in order to further vary the morphology and surface area of the electrode (col. 2, lines 34-51).



As to claim 17, Goldhaber teaches the ablation electrode has a third ablation electrode portion 16 (see Fig. 2 above) configured for mounting on the inner surface of the catheter shaft in an indirect manner (see Fig. 1), the third ablation electrode portion having an outer ablating surface (col. 3, lines 19-23). The third ablation electrode portion is moveable from a first position substantially inside the second ablation electrode portion to a second position substantially outside the second ablation electrode portion as shown in Figs 1 & 2 (col. 3, lines 32-37).

As to claim 18, Goldhaber teaches a longitudinal catheter shaft as explained in regards to claim 16 above. The device, including the longitudinal catheter shaft, is for

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positioning an ablation electrode within a patient's body (col. 3, lines 32-41). The first ablation electrode and the second ablation electrode are directly and indirectly, respectively, mounted on the inner surface of the catheter shaft as seen in Fig. 1.

As to claim 32, Goldhaber teaches the first ablation electrode portion and the second ablation electrode portion are electrically connected (Fig. 3, col. 3, lines 15-18).

10. **Claim 19** is rejected under 35 U.S.C. 103(a) as being unpatentable over Goldhaber (USPN 5,234,429), in view of Turkel (USPN 5,354,296), as applied to claim 18 above, in view of Silvestrini (WO 95/20360).

As to claim 19, Goldhaber as modified by Turkel does not expressly teach a pull wire configured to move the second electrode portion. However, Silvestrini teaches a wire configured to move a second electrode portion (pg. 7, ¶ 2) of a telescoping electrode device that is capable of being pulled or pulling the second electrode portion since it steers the second electrode portion. It would have been obvious to one of ordinary skill in the art at the time of the invention to implement a pull wire to move the second electrode portion of Goldhaber since Silvestrini teaches this feature (pg. 7, ¶ 2) and in order to implement an alternative and simpler method of actuating the movement of the electrode portions.

Response to Arguments

Applicant's arguments with respect to all pending claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BENJAMIN LEE whose telephone number is (571)270-1407. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571)-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/B. L./ 11/19/2009
Examiner, Art Unit 3739

/Linda C Dvorak/
Supervisory Patent Examiner, Art
Unit 3739